

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**

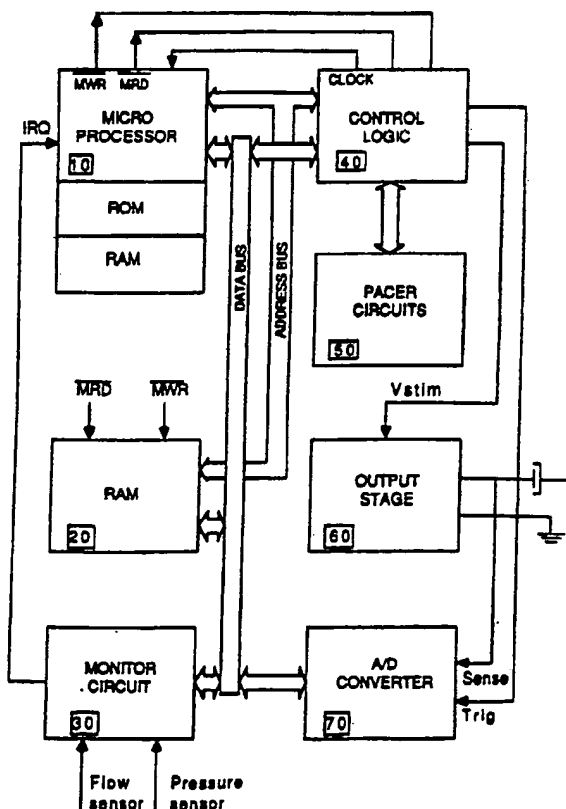


INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification⁴ : A61N 1/362	A1	(11) International Publication Number: WO 89/ 01803 (43) International Publication Date: 9 March 1989 (09.03.89)
(21) International Application Number: PCT/SE88/00446 (22) International Filing Date: 31 August 1988 (31.08.88) (31) Priority Application Number: 8703372-6 (32) Priority Date: 31 August 1987 (31.08.87) (33) Priority Country: SE (71)(72) Applicant and Inventor: LAGERGREN, Hans [SE/SE]; Östermalmsgatan 89, S-114 59 Stockholm (SE). (74) Agents: HENNINGSSON, Gunnar et al.; Bergling & Sundbergh AB, Box 7645, S-103 94 Stockholm (SE).		(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent), DK, FI, FR (European patent), GB (European patent), IT (European patent), JP, LU (European patent), NL (European patent), NO, SE (European patent), US. Published <i>With international search report.</i>

(54) Title: PACEMAKER SYSTEM**(57) Abstract**

An implantable pacemaker system comprises a pulse generator having a memory function and an electrode to be introduced into the heart of a patient. The electrode is connected to the pulse generator via an implantable electrode lead. The system monitors intracardiac ECG. The pulse generator stores the ECG thus monitored in its memory continuously, so that the memory holds ECG data relating to a predetermined elapsed period of time. Means detect death or syncope of the patient and in response thereto stop the storage procedure, at least after a second predetermined period of time has elapsed following said detection.



FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	ML	Mali
AU	Australia	GA	Gabon	MR	Mauritania
BB	Barbados	GB	United Kingdom	MW	Malawi
BE	Belgium	HU	Hungary	NL	Netherlands
BG	Bulgaria	IT	Italy	NO	Norway
BJ	Benin	JP	Japan	RO	Romania
BR	Brazil	KP	Democratic People's Republic of Korea	SD	Sudan
CF	Central African Republic	KR	Republic of Korea	SE	Sweden
CG	Congo	LI	Liechtenstein	SN	Senegal
CH	Switzerland	LK	Sri Lanka	SU	Soviet Union
CM	Cameroon	LU	Luxembourg	TD	Chad
DE	Germany, Federal Republic of	MC	Monaco	TG	Togo
DK	Denmark	MG	Madagascar	US	United States of America
FI	Finland				

PACEMAKER SYSTEM

Transvenous intracardiac stimulation with an implanted pacemaker is an established and common treatment for certain cardiac arhythmias. The intention with this treatment is to keep the patient free from symptoms and if possible to prevent an too early death. The simplicity of the surgical intervention allows rather wide indications for this kind of treatment.

Many patients (12-40%) faint or die suddenly and unexpectedly in spite that they are provided with a pacemaker that functions well. This sudden and unexpected syncope or death can occur at any time and place.

Often the relatives refuse an autopsy. However, even if an autopsy is performed it is often impossible to find the cause of sudden death except in cases of lungemboli, recent cardiac infarction or a cardiac or vascular rupture. The cause of an unexpected syncope may also be difficult to ascertain afterwards.

Cardiac pacemakers from many manufactures are today able to sense and to store certain parameters such as the numbers of electrical impulses for stimulation of the heart, which may or may not produce cardiac contractions, and also to store the electrical activity (Ecg) of the spontaneous cardiac rythm. These registrations can be recorded and printed out from an implanted pacemaker with a help of telemetry. Likewise the parameters that are to be registered can also be programmed from the outside through telemetry.

Before a patient with an implanted pacemaker is burried or cremated it is generally demanded that the impulse generator is removed from the body. According to the invention is suggested that the pacemaker system is constructed in such a way that the pacemaker senses and records the cardiac rythm i.e. the intracardiac Ecg at least at the time of death or syncope and also during a pred terminated time (f r instance 48 h urs) befor the event and that this recording later can be

read out from the impulse generator, preferably after it has been removed from the body or alternatively with the use of telemetry while the impulse generator still remains in the patient.

5 According to a preferred construction the cardiac rythm after death or syncope is recorded during a predetermined time. This time period may for instance be of the magnitude 10 minutes up to 1 hour. With this kind of construction it is advantageous to have the pacemaker to record the time of
10 sensed death or syncope relative to other recordings in such a way that one with certainty can separate recordings before and after sensed death or syncope.

 The fact that the thus recorded cardiac rythm, i.e. pacemaker induced or spontaneous rythm, may be studied after-
15 wards thus makes it possible to obtain better clarification of the cause of death or syncope.

 Death occurs when the heart has ceased to pump blood out into the circulation, i.e. when circulation stops. Circulation, i.e. the flow of blood is kept up by the pumping capacity of the heart. By means of its pumping capacity the
20 heart of a living person produces a flow of blood, pulsations and a blood pressure.

 According to the invention one of these signs of circulation is preferably taken advantage of in order to verify
25 the particular recordings of the pacemaker. More specifically, the disappearing of such a sensed sign of circulation at death or syncope is used to secure the recording according to the invention.

 Methods or techniques for the sensing of pressure, flow
30 or pulsations for instance in an artery are available and are easily applicable. Such parameters can also be obtained from a vein. The sensing of one of these parameters may either be taken from the outside of the vessel or from its inside. A dissection and visualization of a vessel such as an artery is
35 a simple surgical procedure esp cially during an operation upon the h art on a patient when at th same time a pacemaker

is to be implanted. Sensors which for instance are placed on to or into an artery can easily be connected with the pacemaker for instance through an implanted conductor lead.

5 The pumping of the heart can also be sensed directly inside the heart with a suitable sensor, such as a pressure sensor, which preferably can be integrated with and introduced together with an electrode belonging to the pacemaker system.

10 It is of course also possible to have the pacemaker sense the electric activity of the heart (Ecg) in a suitable way, a detected disappearing or change of such electric activity during a certain period then securing the desired recording according to the invention.

15 It should be realized that the memory capacity of the impulse generator for recordings according to the invention preferably should be such that it corresponds to the total time during which recording should be done. When the memory is full the oldest recordings should automatically be removed in order to give space for new recordings according to a rolling schedule.

20 The pacemaker system according to the invention will now be described in more detail by way of an exemplifying embodiment while referring to the enclosed drawing, the single figure of which shows a schematic block diagram of a pacemaker system embodying the invention.

25 Block 10 is a microcomputer hereafter referred to as MCU. A preferred MCU for use in the application of this invention as a part of a programmable cardiac pacer is the HD6301 micro processor made by Hitachi. It offers design advantages of high speed, extremely low power consumption, internal 16 bit timer and registers.

30 An external 8 bit address bus and an 8 bit bidirectional parallel data bus are used for all parallel data communications between CPU and external logic, memory, etc. There are timing signals Clock, MRD, MWR and IRQ.

35 Clock is the principle timing signal, input from a

clock found in the control logic block 40 and controlled by logic within that controller.

5 The frequency of the clock may be up to 2 Mhz, but for this application is 76.8 KHz. IRQ is an input for the MCU and when activated it will start a sequence or action initiated by the monitor circuit block 30. The remaining pins are control pins, only two of which are illustrated here. MRD and MWR control the memory operation.

10 Although only internal ROM and RAM of MCU 10 and one RAM block 20 are shown, it is understood that there is no limitation on the amount of memory, subject only to design considerations. As further shown in the Fig. the output of control logic block 40, which is a timing signal presented as Vstim, is connected to a conventional or advanced output stage block 60 for developing an output signal to be delivered to a patient's heart.

It is to be understood that for a pacemaker application other conventional circuitry is incorporated, including timing logic for determining the rate and circumstances for delivering output pulses; an input path for receiving means for receiving external program signal and modifying operating parameters in accordance with such external signals; etc. All these functions are conventional and well described in the patent literature, and are represented by pacemaker circuits block 50 which is shown communicating with control logic block 40. The A/D converter represented by block 70 is used to convert the measured input signal into a digital 8 bit word, the timing and measuring intervals being controlled by control logic block 40. For the measuring intervals in application, it is understood that there is no limitation on the speed, subject only to design considerations. Measuring interval in this application is 3.33 msec. An 8 bit word representing the value of the input signal related to time is via the data bus transported for storage into RAM 20 where it replaces in a location pointed by the MCU previous measured data. Usage of a RAM capacity of 64 Kbytes, which requires

20
25
30
35

two commercially available as 32 Kbyte circuits, allows then approx. 218 sec history storage of intracardiac signals.

Storage of data is arranged in such a way by the micro-computer program that the oldest available data is replaced by the last measured data.

Replacement of data will be halted in case one of the situations as described in the claims will occur.

Flow and pressure sensor detection means as used in claims 2 and 3 are conventional and well described in the patent literature.

Monitoring the change of the electrical activity of the heart in response to death of the patient can be done by means of morphology recognition on slew rate by using the calculated moving average.

Alterations and modifications are of course possible within the scope of the invention as defined by the following patent claims. For instance the pacemaker system may also include a function for cardiac defibrillation.

CLAIMS

1. An implantable pacemaker system, comprising a pulse generator having a memory function and at least one electrode to be introduced into the heart of a patient, preferably transvenously, the electrode being connected to the pulse generator via an implantable electrode lead, *characterized* in that it is arranged - in a manner previously known per se - to monitor intracardiac ECG; the pulse generator is arranged continuously to store the ECG thus monitored in its memory so that the memory holds ECG data relating to a predetermined elapsed period of time; and means are arranged for detecting death or syncope of the patient and in response thereto to stop said storage procedure, at least after a second predetermined period of time has elapsed following the detection of the death or syncope of the patient.

2. A pacemaker system according to claim 1, *characterized* in that said monitoring means are arranged for monitoring a parameter dependent on the pumping activity of the heart.

3. A pacemaker system according to claim 2, *characterized* in that said monitoring means are arranged to monitor a circulation parameter, such as blood pressure, blood flow or pulsations.

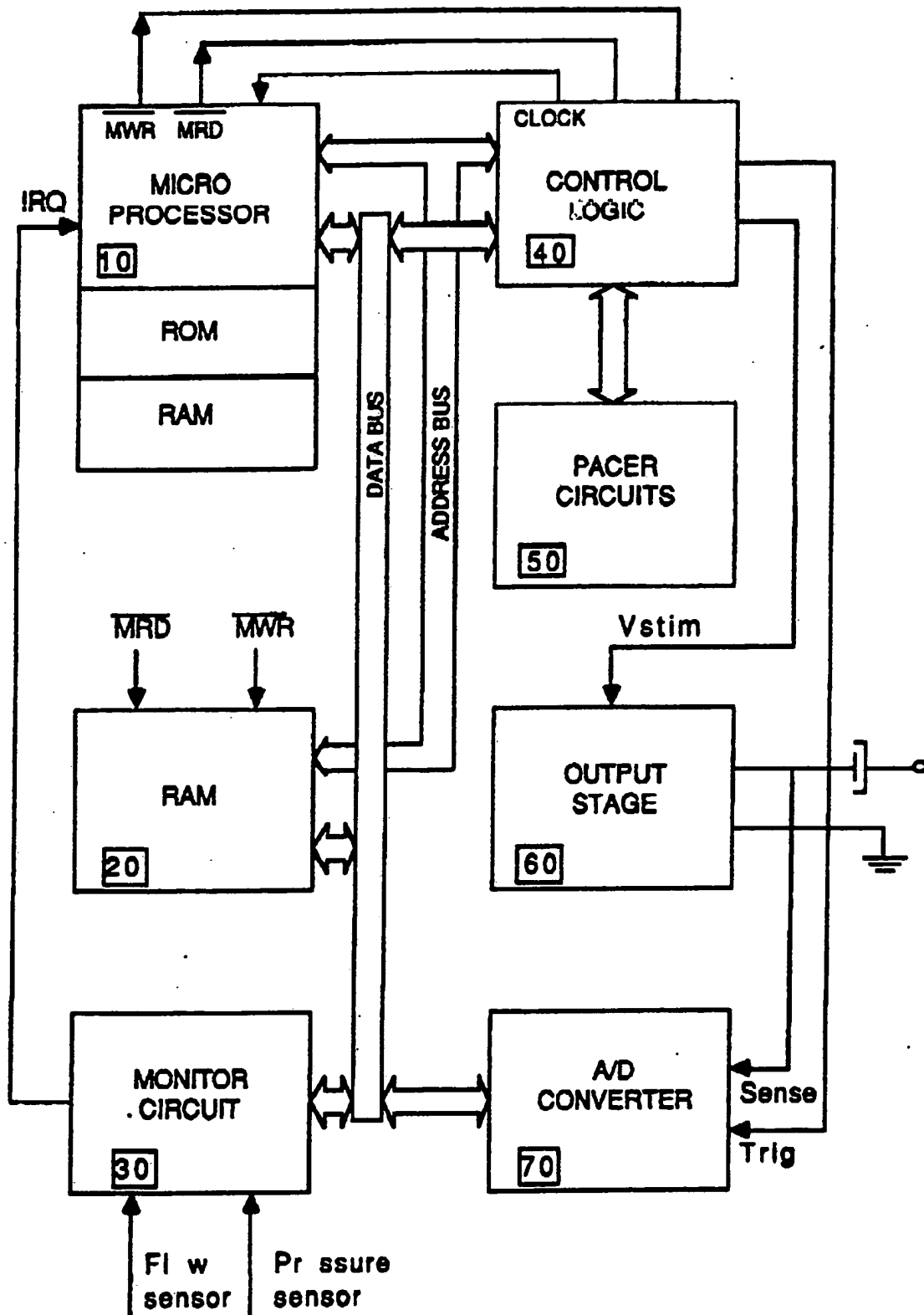
4. A pacemaker system according to claim 3, *characterized* in that said monitoring means comprise a sensor adapted for being applied in conjunction with an artery and connected to the pulse generator via an implantable connection lead.

5. A pacemaker system according to claim 1, *characterized* in that said monitoring means are arranged for monitoring a change of the electrical activity of the heart responsive to the death or syncope of the patient.

6. A pacemaker system according to claim 1, 2 or 5, *characterized* in that said monitoring means comprise a sensor to be introduced into the heart and connected to the pulse generator via an implantable connection lead.

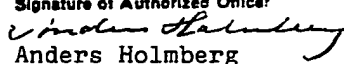
7. A pac maker system according to claim 6, *characterized* in that said connection lead and said electrode lead are integrated.

5 8. A pacemaker system according to anyone of the preceding claims, *characterized* in that the pulse generator is arranged to store the time of the detection of the death or syncope of the patient relative to said ECG data.



INTERNATIONAL SEARCH REPORT

International Application No PCT/SE88/00446

I. CLASSIFICATION & SUBJECT MATTER (if several classification symbols apply, indicate all) *		
According to International Patent Classification (IPC) or to both National Classification and IPC <u>4</u>		
A 61 N 1/362		
II. FIELDS SEARCHED		
Minimum Documentation Searched *		
Classification System	Classification Symbols	
IPC 4	A 61 N 1/36, 1/362-1/378	
US C1	<u>128</u> :419P, 419PG, 419PT, 695-700, 702-712	
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched *		
SE, NO, DK, FI classes as above		
III. DOCUMENTS CONSIDERED TO BE RELEVANT *		
Category *	Citation of Document, ** with indication, where appropriate, of the relevant passages **	Relevant to Claim No. **
A	US, A, 4 513 743 (VAN ARRAGON ET AL) 30 April 1985 See col. 1, lines 50-63, col. 7, lines 39-60	1-8
A	US, A, 4 601 291 (BOUTE ET AL) 22 July 1986	
<p>* Special categories of cited documents: **</p> <p>"A" document defining the general state of the art which is not considered to be of particular relevance</p> <p>"E" earlier document but published on or after the international filing date</p> <p>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</p> <p>"O" document referring to an oral disclosure, use, exhibition or other means</p> <p>"P" document published prior to the international filing date but later than the priority date claimed</p> <p>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</p> <p>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</p> <p>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art</p> <p>"&" document member of the same patent family</p>		
IV. CERTIFICATION		
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report	
1988-11-10	1988 -11- 15	
International Searching Authority	Signature of Authorized Officer	
Swedish Patent Office	 Anders Holmberg	